

ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' Amendments

- 1) Acknowledgment is made of Applicants' amendments filed 08/02/10 and 08/31/10 in response to the non-final Office Action mailed 03/01/10.

Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by attorney Timothy Torchia in a telephonic interview on 03 November 2010.

This application has been amended as indicated below:

(A) Claims 1-7 and 9-17 have been canceled.

(B) New claims 18-27 have been added as indicated below:

--Claim 18 (New). A method of treating obesity in an obese human subject in need of said treatment consisting essentially of administering to said obese subject a therapeutically effective amount of pramlintide to decrease body weight after 4 four weeks of said treatment in said obese human subject from the body weight of said obese patient prior to said treatment, wherein said pramlintide is present in a composition comprising a pharmaceutically acceptable carrier, wherein from 0.5 to 2.0 mg/day of said pramlintide in said composition is administered to said obese subject from 1 to 4 times a day.

Claim 19 (New) The method of claim 18, wherein said composition is administered two times per day.

Claim 20 (New). The method of claim 18, wherein said composition is administered three times per day.

Claim 21 (New). A method of treating obesity in an obese human subject in need of said treatment comprising administering to said obese subject a composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of an obesity-relief agent consisting of pramlintide to decrease body weight after 4 four weeks of said treatment in said obese human subject from the body weight of said obese patient prior to said treatment, wherein from 0.5 to 2.0 mg/day of said pramlintide in said composition is administered to said obese subject from 1 to 4 times a day.

Claim 22 (New). The method of claim 21, wherein said composition is administered three times per day.

Claim 23 (New). A method of treating obesity in an obese human subject in need of said treatment comprising administering to said obese subject a therapeutically effective amount of pramlintide to decrease body weight after 4 four weeks of said treatment in said obese human subject from the body weight of said obese patient prior to said treatment, wherein said pramlintide is not administered in conjunction with another obesity-relief agent, wherein from 0.5 to 2.0 mg/day of said pramlintide is administered to said obese subject from 1 to 4 times a day.

Claim 24 (New). A method of treating obesity in an obese human subject in need of said treatment comprising administering to said obese subject a therapeutically effective amount of a composition consisting essentially of pramlintide to decrease body weight after 4 four weeks of said treatment in said obese human subject from the body weight of said obese patient prior to said treatment, wherein from 0.5 to

2.0 mg/day of said pramlintide is administered to said obese subject from 1 to 4 times a day.

Claim 25 (New). The method of claim 18, 21, 23 or 24, wherein said pramlintide is pramlintide trifluoroacetate, pramlintide acetate, or pramlintide-HCl.

Claim 26 (New) The method of claim 21, 23 or 24, wherein said composition is administered two times per day.

Claim 27 (New). The method of claim 21, 23, or 24, wherein said composition is administered three times per day.

Status of Claims

- 3)** Claims 1-7 and 9-17 have been amended via the amendment filed 09/31/10.
Claims 1-7 and 9-17 have been canceled via this Examiner's amendment.
New claims 18-27 have been added via this Examiner's amendment.
Claims 18-27 are pending and are under examination.

Rejection(s) Moot

4) The rejection of claims 7, 14, 16 and 17 made in paragraph 26 of the Office Action mailed 02/11/08 and maintained in paragraph 11 of the Office Action mailed 04/30/08 and in paragraph 9 of the Office Action mailed 03/01/10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34 and 35 of the US patent 5,686,411 issued to Gaeta *et al.* ('411, of record) as evidenced by Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record), is moot in light of light of the cancellation of the claims.

5) The rejection of claims 7, 14 and 16 made in paragraph 27 of the Office Action mailed 02/11/08 and maintained in paragraph 12 of the Office Action mailed 04/30/08 and in paragraph 10 of the Office Action mailed 03/01/10 under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 11 and 13 of US patent 5,321,008 issued to Beumont *et al.* as evidenced by Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record) and Rink *et al.* (US 5,739,106, of record) ('106), is moot in light of light of the cancellation of the claims.

6) The rejection of claims 1, 7, 14 and 16 and the dependent claims 2-6, 9-13, 15 and 17 made in paragraph 28 of the Office Action mailed 02/11/08 and maintained in paragraph 13 of the Office Action mailed 04/30/08 and in paragraph 11 of the Office Action mailed 03/01/10 under 35 U.S.C § 112, first paragraph, as containing new matter, is moot in light of light of the cancellation of the claims.

7) The rejection of claims 1-7 and 9-17 made in paragraph 29 of the Office Action mailed 2/11/08 and maintained in paragraph 14 of the Office Action mailed 04/30/08 and in paragraph 12 of the Office Action mailed 03/01/10 under 35 U.S.C § 112, first paragraph, as being non-enabling with regard to the scope, is moot in light of light of the cancellation of the claims.

8) The rejection of claims 1-7, 9-14, 16 and 17 made in paragraph 33 of the Office Action mailed 02/11/08 and maintained in paragraph 15 of the Office Action mailed 04/30/08 and in paragraph 13 of the Office Action mailed 03/01/10 under 35 U.S.C § 102(a) as being anticipated by Kolterman *et al.* (WO 96/40220, of record) as evidenced by Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record), is moot in light of light of the cancellation of the claims.

9) The rejection of claims 7, 14 and 16 made in paragraph 34 of the Office Action mailed 02/11/08 and maintained in paragraph 16 of the Office Action mailed 04/30/08 and in paragraph 14 of the Office Action mailed 03/01/10 under 35 U.S.C § 102(e)(2) as being anticipated by Beumont *et al.* (US 5,321,008, of record) ('008)

as evidenced by Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record), is moot in light of light of the cancellation of the claims.

10) The rejection of claims 7, 14, 16 and 17 made in paragraph 35 of the Office Action mailed 02/11/08 and maintained in paragraph 17 of the Office Action mailed 04/30/08 and in paragraph 15 of the Office Action mailed 03/01/10 under 35 U.S.C § 102(e)(2) as being anticipated by Gaeta *et al.* (US 5,686,411, of record) ('411) as evidenced by Tsanev (*Vutr. Boles* 23: 12-17, 1984, abstract, of record), is moot in light of light of the cancellation of the claims.

11) The rejection of claims 1-7, 9, 11-14, 16 and 17 made in paragraph 36 of the Office Action mailed 02/11/08 and maintained in paragraph 18 of the Office Action mailed 04/30/08 and in paragraph 16 of the Office Action mailed 03/01/10 under 35 U.S.C § 102(b) as being anticipated by Kolterman *et al.* (*Diabetologia* 39: 492-499, April, 1996, of record) (Kolterman *et al.*, 1996) as evidenced by Itasaka *et al.* (*Psychiatr. Clin. Neurosci.* 54: 340-341, June 2000, of record), is moot in light of light of the cancellation of the claims.

Remarks

12) Claims 18-27, now renumbered as claims 1-10 respectively, are allowed.

New claims 18-27 find support in the canceled claims 1, 4, 5, 7, 9, 10 and 14-17 respectively.

13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

14) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA and CANADA) or 571-272-1000.

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's acting supervisor, Pat Duffy, can be reached on (571) 272-0855.

/S. Devi/
Primary Examiner
AU 1645

November, 2010